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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,533	07/25/2003	Donald Lynn Bissett	9332	2912

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EXAMINER

ROBERTS, LEZAH

ART UNIT	PAPER NUMBER
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1612

MAIL DATE	DELIVERY MODE
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03/12/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/627,533	Applicant(s) BISSETT ET AL.	
	Examiner LEZAH W. ROBERTS	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4 and 6-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4 and 6-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the Request for Continued Examination filed December 7, 2007. All previous rejections have been withdrawn unless indicated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejection)

Claims 1-10 were rejected under 35 U.S.C. 103(a) as being unpatentable over Stoltz et al. (US 2005/0118119) in view of Chevalier et al. (US 2002/0192169). This rejection is maintained in regards to claims 1, 4 and 6-10.

Applicant's Arguments

Applicant has amended the claims to include the amount of acyl amino acid and B3 that is include in the compositions. Applicants assert that the combination of N-acyl amino acid and Vitamin B3, at the claimed levels leads to surprising and unexpected permeation results and therefore, it would not have been obvious to modify the disclosure of the cited reference to arrive at the claimed invention. Applicant asserts increased permeation of the composition to the skin lead to a higher concentration of the active at the desired site. This argument is not persuasive.

The Declaration of Gary Kelm is submitted to demonstrate unexpected result when acyl-undecylenoyl- phenylalanine is mixed with niacinamide. The compositions comprise an oil-in-water emulsion containing 5% niacinamide with and without 1% Sepi-White dissolved in the oil phase. The result for skin permeation test was reported. Results for the test were obtained by radiolabeling niacinamide and determining how much niacinamide was absorbed by the receptor, skin and residual product not absorbed. The mean amount of product absorbed at the receptor and the skin was reported as well as the SEM. The total permeated for the emulsion without Sepi-white was 53.9, SEM being 4.0. The total permeated for the emulsion with Sepi-white was 63.9, SEM being 8.3.

Examiner's Response

Examiner disagrees in regards to the amount of components in the compositions. The reference discloses undecylenoyl-L-phenylalanine comprises 1 to 3% of the disclosed examples, which encompasses the instant claims. In regards to vitamin B₃, the actives included in Stoltz et al. comprise 1.00% to 2.00% of the compositions (see Examples 2 and 5). It may be concluded that vitamin B₃ may also be included in the compositions in this range. Even if this was not the case it would take no more than routine experimentation by one skilled in the art to determine the appropriate amount of vitamin B₃ needed for optimal efficacy.

In regards to the Declaration, the Declaration of Gary Kelm is insufficient to overcome the instant rejection. The data that is disclosed is not commensurate in scope

Art Unit: 1612

with the instant claims. The claims recite undecylenoyl-L-phenylalanine comprises 0.0001% to 25% of the compositions and B₃ comprises from about 2% to about 5% of the compositions. Applicant has only disclosed results for 1% Sepi-White and 5% niacinamide. Furthermore, niacinamide is a component of B₃ and does not represent all the components that are encompassed by the recitation of vitamin B₃. Applicant has also not disclosed what is in Sepi-White and therefore it cannot be determined how much undecylenoyl-L-phenylalanine is used in the compositions.

The Declaration provides the Mean and SEM data for the receptor, total skin and total permeated. The Declaration does not provide data for the residual product, which Applicant has reported was analyzed. Furthermore in regards to the receptor, the two emulsions appear to be the same in view of the SEM values, which is concluded to be the standard error for the mean since Applicant does not seem to define what SEM is. There also appears to be some overlap with the total skin results having values of 21.7 (SEM 3.5) w/o Sepi-White and 27.9 (SEM 5.8) with Sepi-White. In regards to the total permeated, the values of 53.9 (SEM 4.0) without Sepi-White and 63.9 (SEM 8.3) with Sepi-White appear to overlap, considering the SEM values, and may be considered substantially the same. Since the values are very close in view of the SEM values, it cannot be concluded that these are unexpected results. Furthermore it has been reported in the art that acyl-phenylalanines are penetration enhancers¹. Therefore it would have been expected that the compositions comprising an acyl-phenylalanine

¹ Stern et al., US 6,086,918, col. 9, line 46.

Art Unit: 1612

would cause an increase in permeation in comparison with those that don't. Therefore the Declaration is insufficient to overcome the rejection.

Claims 1, 4 and 6-10 are rejected.

No claims allowed.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 1612

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. W. R./
Examiner, Art Unit 1612

/Frederick Krass/

Application/Control Number: 10/627,533

Page 7

Art Unit: 1612

Supervisory Patent Examiner, Art Unit 1612